REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application are respectfully requested in light of the amendments above and the comments which follow.

As correctly noted in the Official Action Summary, Claims 1-12, 15, 16 and 41-64 were pending. By the present response, Claims 1, 41 and 43 have been amended. Thus, upon entry of the present response, Claims 1-12, 15, 16 and 41-64 remain pending and await further consideration on the merits.

Support for the foregoing amendments can be found, for example, in at least the following locations in the original disclosure: paragraphs [0073], [0104] and [0105].

Entry of the forgoing is appropriate pursuant to 37 C.F.R. §1.116 for at least the following reasons. First, the amendments raise no new issues that would necessitate further search and/or substantive reexamination. Second, the amendments clearly overcome the grounds of rejection.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 41, 43-45, 55, 63 and 64 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,241,316 to Evans et al. (hereafter "Evans").

The present invention is directed to compositions which are formulated such that they provide certain advantages and benefits for applications such as a moldable biocompatible implant. Compositions formed according to the principles of the present invention provide certain benefits and advantages relative to conventional biocompatible implant materials.

For example, calcium phosphate cements, which can be biodegradable, have been utilized as biocompatible implants. However, such materials often lead to the formation of dense or solid masses that inhibit osteo-conduction (see, e.g., paragraph [0006]; this is essentially the construction described by Ricci et al). Moreover, implants which are solid and contain only small pores can be disadvantageous in that the natural bone surrounding the implant cannot integrate into the implant unless the implant is degraded. Conventional osteo-inductive and/or osteo-conductive implants have limited use for restoring the wound or defect to a more natural condition, they fill rather than heal the defect (see, e.g., paragraph [0007]; this is essentially the construction disclosed by *Evans et al.*).

Amended Claim 41 recites:

> A composite implant mass comprising:
> a structural component, the structural component comprising a plurality of biocompatible synthetic non-polymeric granules, the granules being regularly-sized, regularly shaped, or spherical, and the granules having an equivalent diameter of about 100 μm to about 4,000 μm;
> a biocompatible polymer on at least a portion of each of the granules; and
> a plasticizer in an amount sufficient to condition at least a portion of the biocompatible polymer so that the granules of the implant mass are bound to each other by adhesion between the biocompatible polymer disposed on adjacent granules, and the implant mass is plastically deformable.

Amended Claim 43 recites:

> A composite matrix comprising:
> a structural matrix, the structural matrix comprising a plurality of biocompatible synthetic non-polymeric granules bound to each other, at least in part, by adhesion between a biocompatible polymer coating formed on each of the adjacent granules; and
> an open porous region comprising macropores between adjacent coated granules;

> wherein the structural matrix does not contain any bone particles.

For at least the reasons noted below, this rejection should be withdrawn.

Initially, the Official Action alleges that:

> Evans et al. disclose a moldable implant composition including: a plurality of biocompatible synthetic non-bone particles such as ceramics or calcium phosphate or calcium sulfate having a particle size of about 100 microns; a biocompatible polymer such a polylactide or polycaprolactone; a plasticizer such as caprolactone; and a biologically active substance such as a growth factor wherein the composition can be delivered by injection or preformed as an implant for surgical insertion (Figs. 15-18, col. 16, lines 20-61, col. 18, lines 63-67, col. 19 and col. 20, lines 1-51). (Official Action at page 2).

Contrary to the above assertion, Evans fails to disclose granules having an equivalent diameter of about 100 microns. Instead, Evans discloses that certain embodiments of a matrix has a pore size of greater than 100 microns (see, e.g., Claim 1). Thus, Evans fails to anticipate at least this aspect of Claim 41.

Moreover, the Official Action alleges that:

> "at least a portion of each granule or particle" of Evans et al. would be coated with polymer when the non-polymeric granules are mixed with a polymer and the plasticizer. (Official Action at page 6).

Evans fails to explicitly disclose a coating on each granule. Thus, the Official Action relies on inherency in an attempt to establish that a coating is formed on at least part of each of the granules in Evans.

"Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)) (emphasis in original).

See also Ex Parte Whalen, 89 USPQ2d 1078 (BPAI 2008). In contrast to Evans, as disclosed in the present specification, the granules are spray-coated in a fluidized bed machine or immersion-coated with the desired polymer (paragraphs [0057] and [0058]) to form a coating on each granule. Such methods ensure that each granule is at least partially coated, whereas simple mixing of a polymer with granules may not result in coating of each granule. Thus, it is not enough to merely mix polymer with granules as in Evans to form a coating on each granule as recited in the present claims. As such, Claims 41 and 43 are not anticipated by Evans because Evans fails to disclose either explicitly or inherently that a coating would be formed on at least a part of each granule of Evans.

To reiterate, because Evans fails to disclose granules having an equivalent diameter of about 100 μm to about 4,000 μm, or a biocompatible polymer on at least a portion of each of the granules as recited in Claim 41, Claim 41 is not anticipated by Evans. Moreover, Claim 43 is not anticipated by Evans because Evans fails to disclose a biocompatible polymer on at least a portion of each of the granules as recited in Claim 43.

Claims 44-45, 55, 63 and 64, which ultimately depend from Claim 43, are also not anticipated by Evans for at least the reasons Claim 43 is not anticipated.

Claims 43-45, 55, 63 and 64 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 6,770,695 to Ricci et al. (hereafter "Ricci").

Specifically, the Official Action alleges that:

> Ricci et al. disclose an implantable or moldable composition including: synthetic calcium sulfate particles having a size greater than 20 microns; a biocompatible or biodegradable polymeric coating on

> the particles wherein the polymer is any type of resorbable polymer (for e.g. polylactides, polydixanones etc.), the weight of the polymer is about 0.1% to about 50% by weight and the thickness of the polymeric coating is 0.5 microns to 100 microns; a plasticizer such as acetone; and a setting agent such as water or saline (col. 3, lines 11-28 and col. 4, lines 5-47). Once solidified in a bone defect, the Ricci et al. composition forms a composite matrix with pores filled with air. (Official Action at page 3).

For at least the reasons noted below, this rejection should be withdrawn.

Claim 43 is not anticipated by Ricci at least because Ricci fails to disclose a plurality of biocompatible synthetic non-polymeric granules bound to each other, at least in part, by adhesion between a biocompatible polymer coating formed on each of the adjacent granules, as recited in Claim 43. To the contrary, Ricci's particles (P) are settled within the matrix (M) formed by the calcium sulfate compound. (Col. 2, lines 65-67). Ricci's particles (P) can include calcium sulfate compound encapsulated in a coating (C) of a resorbable polymer. However, the particles (P) are not bound to each other, at least in part, by adhesion between a biocompatible polymer coating formed on each of the adjacent granules as recited in Claim 43. To the contrary, the particles appear to be bound together by the interconnecting matrix (M). As such, Claim 43 is not anticipated by Ricci.

Claims 44-45, 55, 63 and 64, which depend from Claim 43, are also not anticipated for at least the reasons Claim 43 is not anticipated.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claims 1-3, 5-9, 11-12, 16, 41-42, 46-54 and 56-62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ricci.

Amended Claim 1 recites:

> A moldable implant mass composition for use in repairing a bone defect in a living organism, comprising:
>
> a plurality of biocompatible synthetic non-polymeric granules, said granules having an equivalent diameter of about 100 μm to about 4,000 μm;
>
> a biocompatible polymer coating at least a portion of the implant mass, the implant mass comprising a composite matrix of the granules bound to each other by adhesion between the biocompatible polymer disposed on adjacent granules, and
>
> macropores between adjacent granules, so as to form an implant mass comprising a plurality of distinct granules coated with said biocompatible polymer, said biocompatible polymer comprising about 4% to about 20% of the total weight of the implant mass; and
>
> a plasticizer in said implant mass in an amount sufficient to condition at least a portion of said biocompatible polymer so that said implant mass is plastically deformable into a desired shape and then hardenable upon removal of at least a portion of said plasticizer from said implant mass.

Under 35 U.S.C. § 103(a), the Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. § 2142. As set forth in M.P.E.P. § 2143, one requirement for establishing a *prima facie* case of obviousness is that the combination of references must teach or suggest all the claim features (Emphasis Added). *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The grounds for rejection clearly fail to satisfy this requirement with respect to the requirements of Claim 1.

With respect to Claim 1, the Official Action alleges that:

> Ricci et al. disclose an implantable or moldable composition including: synthetic calcium sulfate particles having a size greater than 20 microns; a biocompatible or biodegradable polymeric coating on the particles wherein the polymer is any type of resorbable polymer (for e.g. polylactides,

> polydixanones etc.), the weight of the polymer is about 0.1% to about 50% by weight and the thickness of the polymeric coating is 0.5 microns to 100 microns; a plasticizer such as acetone; and a setting agent such as water or saline (col. 3, lines 11-28 and col. 4, lines 5-47).
>
> Ricci et al. disclose particles with a size greater than 20 microns. Ricci et al. also disclose the weight of the polymer to be about 0.1% to about 50% by weight.
>
> Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided particles with sizes in a range of about 100 microns to about 4000 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. (Official Action at pages 3-4).

For at least the reasons noted below, this rejection should be withdrawn.

As noted above, Ricci's particles (P) can include calcium sulfate compound encapsulated in a coating (C) of a resorbable polymer. Ricci's particles (P) are settled within the matrix (M) formed by the calcium sulfate compound. (Col. 2, lines 65-67). However, Ricci's particles (P) are not bound to each other by adhesion between the biocompatible polymer disposed on adjacent granules as recited in Amended Claims 1 and 41. Instead, the particles (P) appear to be bound together through an interconnecting matrix (M). As such, Ricci fails to disclose or suggest all features of Amended Claims 1 and 41 as required, and thus Claims 1 and 41 are patentable over Ricci.

Claims 2-3, 5-9, 11-12, 16, 47-49, 50, and 56-62, which ultimately depend from Claim 1, are patentable for at least the reasons Claim 1 is patentable.

Claims 42, 51-54, which ultimately depend from Claim 41, are patentable for at least the reasons Claim 41 is patentable.

Claim 46, which depends from Claim 43, is patentable at least because Ricci fails to teach or suggest all features of Claim 43 including a plurality of biocompatible synthetic non-polymeric granules bound to each other, at least in part, by adhesion between a biocompatible polymer coating formed on each of the adjacent granules, as discussed above. As such, Claim 43 and Claim 46 which depends therefrom, are patentable over Ricci.

Claim 4 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Ricci in view of Evans on the grounds set forth on page 4 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Claim 4, which ultimately depends from Claim 1, is patentable over the references as combined for at least the reasons Claim 1 is patentable and because Evans fails to remedy the deficiencies of Claim Ricci.

Claim 10 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Ricci in view of U.S. Patent No. 7,001,551 to Meredith (hereafter "Meredith") on the grounds set forth on page 5 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Claim 10, which ultimately depends from Claim 1, is patentable over the references as combined for at least the reasons Claim 1 is patentable and because Meredith fails to remedy the deficiencies of Ricci.

Claim 15 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Ricci in view of U.S. Patent No. 4,430,760 to Smestad (hereafter "Smestad") on the

grounds set forth on page 5 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Claim 15, which ultimately depends from Claim 43, is patentable over the references as combined for at least the reasons Claim 43 is patentable and because Smestad fails to remedy the deficiencies of Ricci.

Claims 42 and 46 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Evans on the grounds set forth on page 6 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

Claim 42, which ultimately depends from Claim 41, is patentable over Evans at least because Evans fails to teach or suggest all features of Claim 41 including granules having an equivalent diameter of about 100 μm to about 4,000 μm or a biocompatible polymer on at least a portion of each of the granules as recited in Claim 41 and discussed in detail above.

Claim 46, which ultimately depends from Claim 43, is patentable over Evans at least because Evans fails to teach or suggest all features of Claim 43 including a biocompatible polymer on at least a portion of each of the granules as recited in Claim 43.

Moreover, under §2144.05(II)(B), only result effective variables can be optimized.

> A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)

Thus, where, as here, the claimed feature is a physical feature, and not a variable that achieves a result recognized by the prior art, it is improper to allege that it would have been obvious to optimize the range thereof. Thus, Claims 42 and 46 are further patentable over Evans.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is earnestly solicited. Should the Examiner feel that any issues remain, it is requested that the undersigned be contacted so that any such issues may be adequately addressed and prosecution of the instant application expedited.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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